

# **IMPORTANT DRUG WARNING**

## ***COUNTERFEITING OF NEUPOGEN®***

May 10, 2001

Dear Health Care Professional:

Amgen Inc. recently became aware of the existence in the U.S. of a counterfeit drug product labeled as Neupogen® 300 mcg vials in ten-pack boxes. In cooperation with the U.S. Food and Drug Administration (FDA), Amgen is informing patients, physicians, pharmacies, and wholesalers about this serious health risk.

**The counterfeit vials examined to date contain a clear liquid  
but no active ingredient.**

The counterfeit product, which is definitely not Neupogen (Filgrastim), was neither manufactured nor distributed by Amgen and may pose a serious health risk to patients.

The following information may help in determining if the product you have is counterfeit or actual Neupogen manufactured and distributed by Amgen. Pharmacists and all other health care providers should examine the product before use.

In order to view pictures illustrating these differences, please log on Amgen's web site at [www.amgen.com/corporate/AmgenNews.html](http://www.amgen.com/corporate/AmgenNews.html).

<b>Features of counterfeit product</b>	<b>Features of authentic Neupogen</b>
Lot number P000948	No such Neupogen lot number exists
Lot number P000890 and expiration 12/02	Lot number P000890 and expiration 02/02
Underside of vial stopper indented	Underside of vial stopper flat
Vial height is approximately 35 mm	Vial height is approximately 34 mm
Patient insert: Is on regular stock paper Has no boxes around drawings Printing on back page is inverted	Patient insert: Is on thin, light-weight, pale blue paper Has boxes around drawings Same orientation printing on front and back
Physician insert: Is on regular stock paper Dimensions are too small, unfolded	Physician insert: Is on thin, light-weight paper Dimensions are 16"x24", unfolded
Underside of flip-top has 6 dents on metal edge	Underside of flip-top has smooth, even metal edge
Top surface of stopper has a raised round ridge	Top surface of stopper is indented
Label font for product name and concentration is rounder	Label font for product name and concentration is narrower
Font used for lot number and exp on carton is narrower	Font used for lot number and exp on carton is rounder
Brand name on box is lighter, not as bold	Brand name on box is darker and bolder
Poor print quality on label and box	Crisp, high-quality print on label and box

If you receive any product that you suspect is counterfeit, quarantine it and store it under labeled conditions. Please contact FDA promptly at **1 800 835 4709**. If you have questions about Neupogen, please contact Amgen Professional Services at **1 800 772 6436**. Please convey this information to your staff and any others who administer Neupogen. You should instruct them on what to look for and what to do in the event they find a suspect counterfeit vial.

Amgen is cooperating fully with the FDA to investigate this matter and prevent the further distribution of counterfeit product. To Amgen's knowledge, the counterfeit product has only been found in distribution in the U.S.

Neupogen is primarily used to prevent infection, as manifested by febrile neutropenia in cancer patients receiving myelotoxic chemotherapy. Full product information and any updates on this situation are available on the web at [www.amgen.com](http://www.amgen.com).



Martha E. Vincent, Ph.D., FACCP  
Vice President, Corporate Professional Services  
Amgen Inc.

**Other Contact Information:**

U.S. Food and Drug Administration (for press inquiries): (301) 827 6242